

### **Remarks**

Claim 1 has been amended to include the limitations of claim 5. Consistent with this amendment, claims 4-5 have been canceled. Support for these amendments may be found in the claims as originally filed.

New claim 21 has been added. Support for this claim may be found, for example, at the last paragraph on page 4 of the specification as originally filed.

New claim 22 has been added. Support for this claim may be found, for example, at page 5 of the specification.

No new matter is believed to be added by entry of the amendments, upon entry of which, claims 1-3 and 6-22 will be pending.

The Applicants thank Examiner Sasan for acknowledging their claim to priority and for considering the Information Disclosure Statement.

### **Rejections Under 35 U.S.C. §102**

The Applicants acknowledge the anticipation rejections of claims 1-3 over Fildes et al., of claims 1-4 over Yu et al., and of claims 1-4 and 13 over Graham et al. These rejections have been obviated by amendment. Claim 1 now includes the limitations of claim 5, which was not rejected over the cited references. The Applicants kindly request that these grounds of rejection be withdrawn.

### **Rejections Under 35 U.S.C. §103**

The Applicants acknowledge the obviousness rejections of claims 1-6 and 8-12 over Fildes et al. in view of Wunder et al., and of claim 13 over Fildes et al. in view of Wunder et al. and further in view of Graham et al. These rejections are traversed.

The subject matter of claims 1-6 and 8-12 is patentable over Fildes et al. and Wunder et al. Fildes and Wunder disclose divergent polymers, which cannot be substituted for or combined with one another so readily as the Office has asserted. There is no basis in the references that would suggest the substitution, and there is no expectation of success in the substitution. Even if one were motivated to do so, one would not arrive at the subject matter of the claims. The reason provided by the Office in support of the rejection, it is respectfully submitted, mischaracterizes and oversimplifies the teachings of the references.

Fildes discloses a biological agent delivery device based on a hydrophilic / amphipathic linear block copolymer (the “ABABAB polymer”). Fildes’ ABABAB polymer is made of (1) polyethylene glycol, (2) a diisocyanate, and (3) one or more dihydroxy compounds. Fildes col. 4, lines 30-45. The “A” region contains a hydrophilic polyoxyalkylene, and the “B” region contains a hydrophobic polyurethane. Fildes col. 2, lines 35-45.

Fildes discloses that hydrophobic polyurethane region B is formed from (1) a diisocyanate, and (2) one or more dihydroxy compounds. See col. 2, lines 40-55 of Fildes, which states:

“The hydrophobic regions B are composed of a polyurethane which is obtainable in known general manner from a diisocyanate [...] and one or more dihydroxy compounds, for example one or more alkyleneglycols of not more than 6 carbon atoms [...] and/or a short chain oxyalkylated diphenol, for example 1,1'-isopropylidene-bis-p-phenyleneoxy-di-propanol-2.”

Together, the A and B regions make up the Fildes hydrophilic / amphipathic linear block copolymer ABABAB for the delivery of biological agents. Fildes cols. 1 and 2.

Wunder discloses a completely different polymer for a completely different endeavor. Wunder teaches an emulsion product of (1) a vinyl or divinyl monomer and (2) a “reaction product” containing isocyanate groups (col. 1, lines 40-45) for improving the finish of textiles.

The Office asserts that it would be obvious to combine Wunder's reaction product with Fildes' linear copolymer. The Office asserts that "Wunder teaches that the [reaction product] includes suitable polyols such as polyethylene glycol, suitable polyhydric alcohols such as 1,10-decane diol and suitable isocyanates such as 4,4'-dicyclohexyl methane." Office Action page 7, 5<sup>th</sup> full paragraph. The Office asserts that Wunder "suggests" a polyurethane of polyethylene glycol, 1,10-decane diol, and 4,4'-dicyclohexyl methane diisocyanate. Office Action page 7, 4<sup>th</sup> full paragraph. The Applicants kindly submit that these statements by the Office mischaracterize the teachings of Wunder.

In contrast to the Office position, Wunder does not disclose or suggest a polyurethane (or any other polymer) made from polyethylene glycol, 1,10-decane diol, and 4,4'-dicyclohexyl methane diisocyanate. Indeed, Wunder does not disclose or suggest the use of polyethylene glycol and 1,10-decane diol together at all. See col. 2, lines 1-15 of Wunder, which states:

"Any suitable polyol preferably having a molecular weight of from about 500 to about 6,000 may be used including polyhydric polyalkylene ethers, polyhydric polyesters and the like. Specific examples of polyhydric polyalkylene ethers are for example, polyethylene glycol-1000 [...] and the like. Specific examples of polyesters are those obtainable from dicarboxylic acids such as [...] 1,10-decane diol and the like."

In contrast to the Office assertions, Wunder's polyol is either a polyhydric polyalkylene ether (e.g., polyethylene glycol-1000 and the like) or a polyhydric polyester (the product of a dicarboxylic acid and a polyhydric alcohol such as 1,10-decane diol), but not both. Assuming, *arguendo*, that Wunder's reaction product is a polyurethane, that polyurethane cannot simultaneously contain both the polyalkylene ether and the polyhydric alcohol, because it is simply not taught in Wunder. There is nothing in Wunder to support the Office's basis for combining the references, and the rejection cannot be sustained on such grounds.

Even if one were to combine Wunder and Fildes as advanced by the Office, there is no expectation that the combination would be successful. Wunder's polyurethane co-polyalkylene ether or polyurethane co-polyester "reaction product" is not only a different polymer than that described in Fildes, it is disclosed as useful only in the context of forming an aqueous emulsion with a vinyl or divinyl monomer for improving the finish of textiles. One would not expect Wunder's polyurethane co-polyalkylene ether or polyurethane co-polyester to have the same hydrophilic or amphipathic properties as Fildes' ABABAB linear block copolymer. One would not expect Wunder's polyurethane co-polyalkylene ether or polyurethane co-polyester to have the same hydrophobicity as Fildes' polyurethane B region. Indeed, one would not expect Wunder's polyurethane co-polyalkylene ether to have the same hydrophilic/hydrophobic properties as Wunder's polyurethane co-polyester. Thus, expectation of success is lacking, and the rejection cannot be sustained on such grounds.

Finally, even if one were to combine Fildes and Wunder, the result would not be the subject matter as claimed. Wunder's polyurethane co-polyalkylene ether or polyurethane co-polyester does not cure the deficiencies of Fildes. For this and the reasons above, withdrawal of this ground of rejection is kindly requested.

The rejection of claim 13 over Fildes and Wunder and further in view of Graham is traversed. The Applicants acknowledge that Graham discloses polyurethaneurea polymers, but they are quite different from those polyurethanes discussed in Fildes and Wunder. It is also significant that Graham seeks to improve over the linear block amphipathic polymers of Fildes. See, e.g., page 1, lines 17-22 of Graham and also the International Search Report in Graham, wherein GB 1551620 is shown as the GB equivalent of Fildes. Graham teaches that the Fildes polymers are inferior because not all of them are completely insoluble in water. Graham page 1,

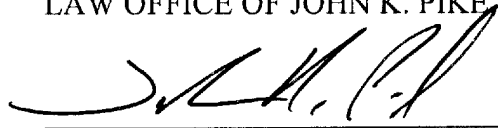
lines 17-22. This is a clear teaching away, and the rejection cannot be sustained over a combination of Fildes and Graham. The Applicants kindly request that the rejection be withdrawn.

Conclusion

This application is now in condition for allowance and issue. An early and favorable indication of same is kindly requested. Should any questions arise regarding the application, the Examiner is kindly invited to telephone the Applicant's undersigned representative at the number below.

Respectfully submitted,

LAW OFFICE OF JOHN K. PIKE, PLLC

A handwritten signature in black ink, appearing to read 'J.K. Pike', is written over a horizontal line.

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